



CSO Council White Paper

Digital clinical safety in the UK, an open and informed position: supporting CSOs to foster a culture of compliance with standards

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Executive summary

Digital clinical safety is becoming increasingly embedded into organisations, and along with it, compliance with the Data Coordination Board standards DCB0129 and DCB0160, which are mandated under the Health and Social Care Act 2012. However, there exists a number of challenges that are limiting the potential impact of the process. A Digital Health Networks CSO Council survey of clinical safety officers, conducted in 2024, highlighted key areas of concern, including a lack of understanding of the clinical safety process and importance of the CSO role, insufficient capacity for digital clinical risk management and lack of senior leadership buy-in. This white paper provides actionable insights to address these concerns, foster a culture of compliance with standards and improve digital clinical safety.

Introduction

Clinical safety officers (CSOs) are integral to the NHS's mission to enhance patient safety and drive technological innovation, as highlighted in the NHS Long Term Plan (ref 1) and the Digital Clinical Safety Strategy (ref 2). The plan and strategy emphasise the importance of digital transformation in delivering safer, more efficient healthcare services. CSOs play a critical role in this vision by ensuring that Health IT (HIT) systems are not only effective but also do not introduce additional risk that could negatively impact citizens. As the NHS increasingly integrates new technologies in line with its long-term goals, CSOs are essential in maintaining compliance with DCB0129/0160 standards, ensuring that these innovations support rather than compromise patient care, and in doing so foster a culture in which safety is at the centre of the design of HIT systems.

NHS England state that:



“It has long been recognised that failures, flaws and unintentional misuse of 'Digital products' have the potential to introduce harm to 'Patients / Service users' when used to support health and social care services.” (ref 3)

These standards were created to establish a systematic approach to identifying, assessing, and mitigating risks associated with the design, build and use of digital technologies in healthcare. They are vital for maintaining high standards of patient safety, particularly as healthcare organisations increasingly integrate novel and more complex IT systems into clinical workflows.

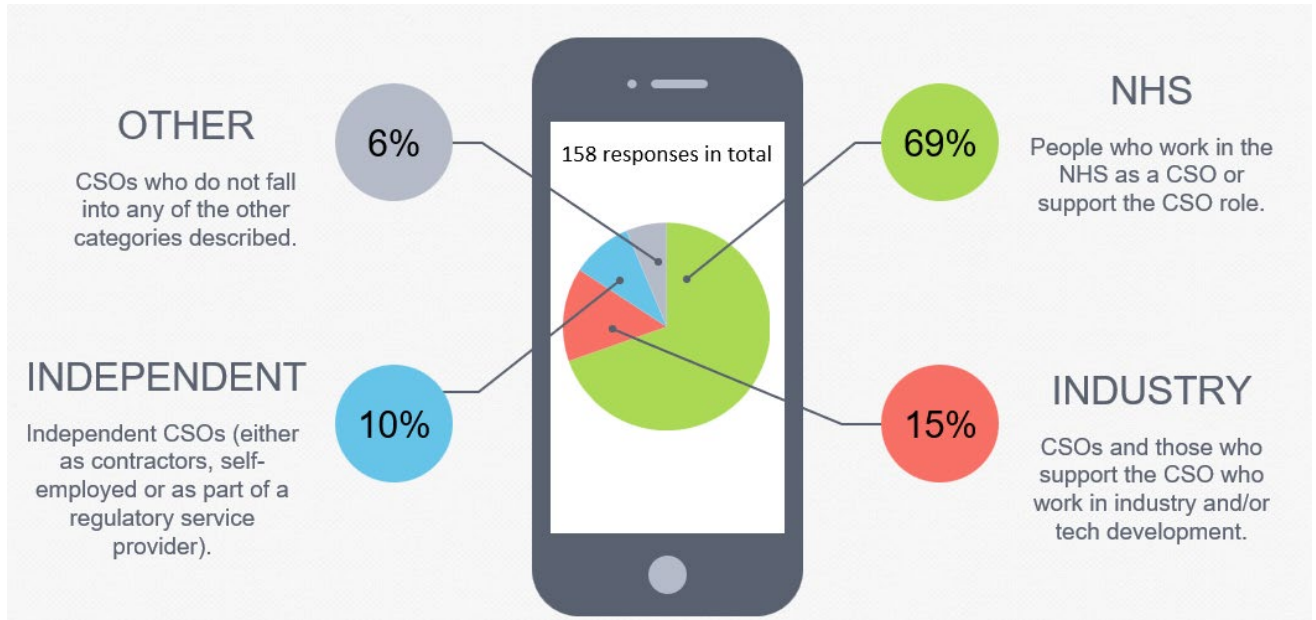
Purpose of the white paper

The purpose of this white paper is to provide insights into the current perceptions of those working within digital clinical risk management (DCRM). Acknowledging that CSOs play a critical role in ensuring that HIT systems meet the DCB0129 and DCB0160 standards, the paper highlights perceived challenges, barriers, opportunities and cultures within DCRM in healthcare organisations, manufacturers and within the independent sector.

The paper presents actionable insights for improving the adoption and effectiveness of CSO roles and ensuring the robust implementation of DCRM processes across the healthcare sector. Improvement in these areas would enhance patient safety and optimise the performance of HIT systems within the UK healthcare system.

Key themes from the ‘Insights Survey’

The Clinical Safety Officer Insights Survey, designed by the Digital Health Networks CSO Council, aimed to assess the current state of digital clinical safety within various sectors and identify key challenges faced by CSOs. Conducted over 25 days (16 August 2024 – 9 September 2024), with 158 respondents from NHS, industry sectors and independent CSOs, the survey provided a comprehensive view of the perceived effectiveness of digital clinical safety practices and highlighted implementation barriers.



Theme 1: Lack of awareness

One of the foremost internal barriers identified is the lack of awareness and understanding of the DCB0129/0160 standards among healthcare professionals, administrative staff and senior leadership teams throughout NHS organisations. Despite the critical importance of these standards, they are frequently perceived as technical and disconnected from the immediate priorities of clinical care. This disconnect can lead to a situation where the standards are seen as a bureaucratic burden rather than a fundamental component of patient safety and digital transformation. Without adequate training and clear communication on the relevance and benefits of these standards, healthcare organisations struggle to foster a culture of compliance, which is essential for effective implementation.

For example, when participants were asked what they perceived the biggest barriers to be with the implementation of DCRM activities with their organisations, 50% and 60% respectively commented: “lack of understanding of the CSO role” and “capacity / awareness of the importance of DCRM”. One participant commented “*it’s tough being seen as the blocker to progress*”.

Theme 2 : Resistance to change



Resistance to change is another significant barrier. Healthcare organisations, particularly larger ones, are often characterised by deeply ingrained practices and protocols. Introducing new standards requires altering existing workflows, reassigning responsibilities, and sometimes disrupting long-standing practices. This disruption can generate resistance at various levels, from frontline staff to senior management. The fear of increased workload, combined with uncertainty about the efficacy and benefits of the new standards, can result in passive or active resistance, further delaying implementation efforts.

Compounding these issues is the insufficient allocation of resources. Implementing DCB0129/0160 standards requires investment in training, technology, and dedicated personnel to oversee compliance. However, the CSO survey highlighted that many NHS organisations operate under tight budgetary constraints, with competing priorities that often push compliance initiatives to the periphery. This lack of resources not only hinders the initial implementation but also undermines ongoing monitoring and maintenance, leading to potential gaps in compliance and, ultimately, patient safety risks. The current funding challenges in the NHS are exacerbating this further. It is important to recognise that resource challenges are also reflected in industry.

Moreover, there is an overwhelming pressure to complete tasks quickly to meet short deadlines, which can lead to shortcuts and superficial compliance with the standards. The healthcare environment is fast paced, with constant demands to deliver services efficiently. This pressure can result in a 'tick-box' approach to compliance, where the focus is on meeting deadlines rather than ensuring that the standards are fully understood and properly integrated into practice. The lack of a well-defined and deliberate process can result in inconsistent application of the standards, with some areas of the organisation complying more rigorously than others, leading to variable levels of safety and quality across the system.

When asked if they felt that digital clinical safety was embedded within the culture of their organisation, only 25% of respondents said 'Yes', with 44% saying 'No'. Many reasons were given for these responses, including:

- *“Not in the NHS generally – I find many assume it’s around GDPR or clinical governance.”*
- *“Not yet, but improving quickly.”*
- *“Now we have aligned it with patient safety standard it’s getting there.”*



- *“Not at all, my manager and team are very good but there is no cultural awareness, leading to things getting missed. Clinical safety is in its infancy in my organisation, and I have been tasked with providing training - which is a big area on top of usual responsibilities but does need to happen. The board is aware and there is support there but needs to be better overall.”*
- *“Improving – slowly.”*

Theme 3 : Training and expertise challenges

The role of a CSO requires a unique blend of clinical knowledge, IT expertise, and an understanding of risk management, making it a specialised position. However, there is a notable shortage of professionals with this combination of skills, creating a bottleneck in the widespread adoption of these critical roles across healthcare organisations. Additionally, the training required to develop such expertise is both time-intensive and resource-demanding, which many organisations may struggle to provide.

This skills gap is further exacerbated by the rapid pace of technological change in healthcare IT, requiring CSOs to continuously update their knowledge to keep pace with emerging risks and regulatory changes. Without sufficient numbers of well-trained CSOs, organisations may find it difficult to fully implement and sustain the standards, potentially leading to gaps in compliance and increased risk to patient safety.

This shortage highlights the need for more focused efforts in recruiting, training, and retaining qualified CSOs to ensure the robust application of the DCB0129/0160 standards across the NHS.

There is also a lack of clarity on the recommended number of CSOs required for organisations, particularly when factoring in variables such as workforce headcount and digital maturity. This absence of standardised benchmarks leaves organisations to interpret their own needs, often resulting in either insufficient or inefficient allocation of clinical safety resources. Establishing evidence-based recommendations would better equip organisations to scale their clinical safety teams effectively, ensuring robust risk management across all digital health initiatives.

For example, when asked the question *‘Within your organisation, do you feel that you have the support of Senior Management / Leaders to enable you to autonomously carry out your CSO duties?’*, only 52% responded positively with a ‘Yes’. Other response categories can be seen in the table below.



Answer	Number of responses	% of total
Yes	82	52
No	35	22
Not Sure	15	9.5
Other	26	16.5
Total Responses	158	100

Some examples of responses found in the 'other' category, include:

- *"[There is] limited understanding of the DCBs and associated requirements amongst leadership within the organisation. Lack of support in ensuring completion of deliverables. Seen as a 'tick-box' exercise."*
- *"Given autonomy but not enough support."*
- *"At times full support until you highlight clinical concerns then the support can disappear."*
- *"Not full time (CSO). Don't have any full time. Have to dip in and out. No one putting CS sign off as a priority."*

Theme 4 : Technical and operational challenges

Applying the NHS DCB0129/0160 standards to both existing and new health IT systems poses significant technical and operational challenges. One of the primary technical difficulties is the integration of these standards into legacy systems, which were often developed without the stringent safety requirements now mandated. These older systems may lack the flexibility or documentation needed to demonstrate compliance, requiring costly and time-consuming modifications or, in some cases, complete overhauls.

For new systems, ensuring compliance from the outset involves embedding complex risk management processes into the software development lifecycle, which can be challenging, particularly for suppliers and organisations with limited experience in clinical safety.

Operationally, there is often a lack of alignment between IT teams and clinical staff, leading to gaps in understanding and communication that can hinder effective implementation. Additionally, the constant evolution of health IT, including frequent updates and new technologies, creates an ongoing challenge in maintaining compliance, as each change or new integration necessitates a thorough review and



potential revalidation under the standards. These challenges highlight the need for robust, adaptable processes and closer collaboration between technical and clinical teams to ensure that safety is consistently prioritised in health IT systems.

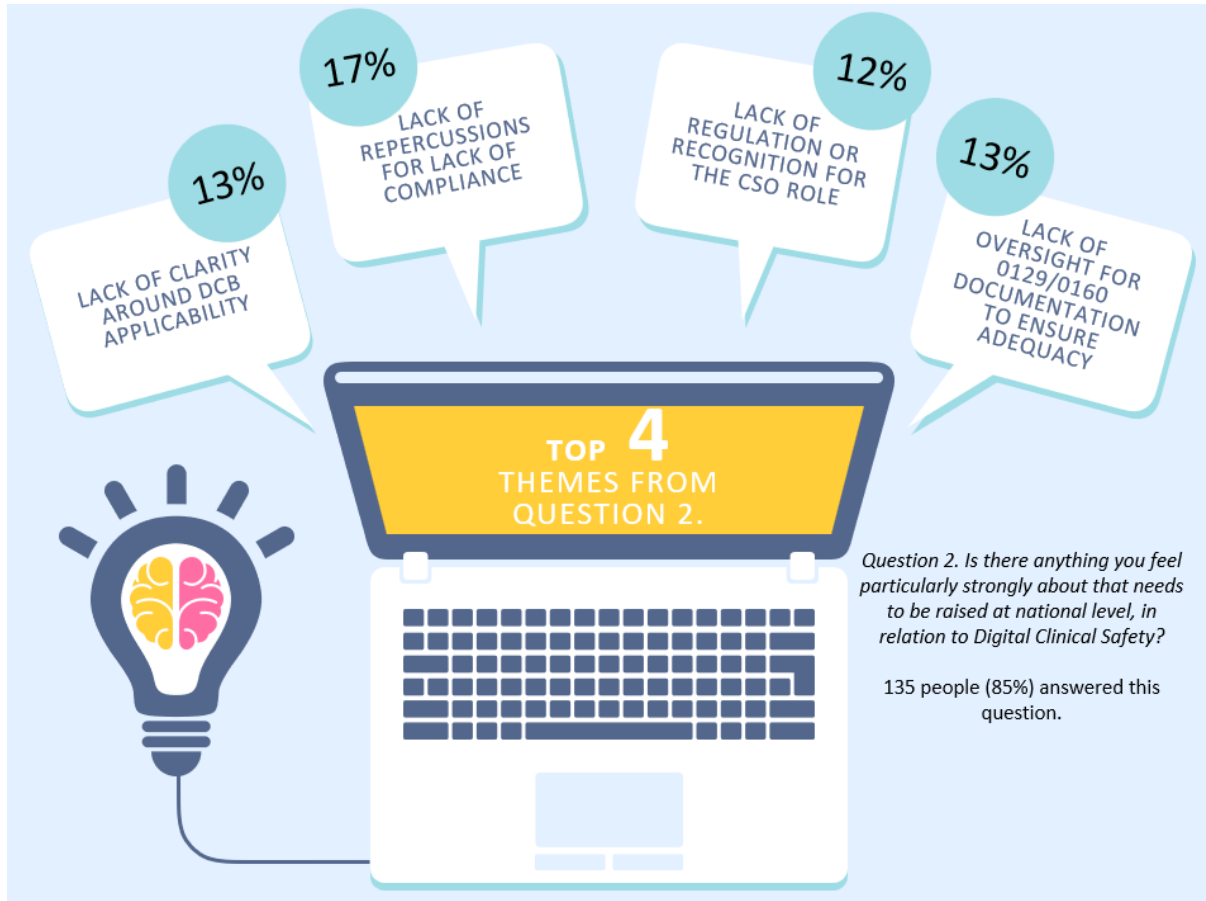
One respondent to the survey explained: “As someone advocating for these processes [DCRM], it can feel like being a lone voice in a sea of other pressing concerns. With so many competing priorities, it can be difficult to ensure that Digital Clinical Safety receives the attention and support it deserves within the broader organisational agenda.”

Theme 5 : Regulatory and compliance issues

Regulatory compliance with the NHS DCB0129/0160 standards presents significant challenges. One major issue is the variability in how different healthcare organisations interpret and implement the standards, leading to uneven levels of compliance across the NHS. This inconsistency is often exacerbated by a lack of clear guidance and support, especially for smaller organisations or those with limited resources. Furthermore, the complexity of the standards themselves can be daunting, requiring specialised knowledge and expertise that may not be readily available within all healthcare settings. The process of achieving compliance is further complicated by the rapid pace of technological advancement, which can outstrip the ability of organisations to keep their systems, processes and clinical risk assessments up to date. These challenges are compounded by the need to balance regulatory demands with the pressures of day-to-day clinical operations, leading to situations where compliance may be seen as a secondary priority, potentially compromising patient safety.

As one respondent to the survey said: “People are uninterested in digital clinical safety as if it's not that important.”

When asked if there was anything they feel particularly strongly about, that needs to be raised nationally in relation to DCS, respondents identified four main areas (see graphic, below).



The lack of clarity around the applicability of the standards was an area of concern for 13% of participants. Nearly 10% of participants also commented on the standards lack of consideration for emerging technologies, such as artificial intelligence (AI), machine learning (ML) and robotics.

Comments also included concerns around the lack of a national reporting system, for when healthcare IT goes wrong.

“When safety concerns and findings are not effectively shared, it leads to isolated information, where critical insights and lessons learned remain confined to specific teams or locations... Moreover, without a structured platform for sharing safety concerns, there is a risk of issues being overlooked.”

Theme 6 : The importance of collaboration



It is important to remember that compliance with the standards isn't entirely at the discretion of the deploying NHS organisation. The standards start, arguably, with the appropriate completion of the DCB0129 deliverables at the supplier / manufacturer organisation. The transfer of this vital information needs to be conducted in a mutually collaborative manner, ensuring those involved are aware of their own roles and responsibilities. It was encouraging to see industry CSOs responding to the 'Insights Survey', with nearly 15% of respondents stating they work within this sector.

Another group of exceptionally valuable individuals, with unique experience and vantage points, are those who work in the regulatory space independently. Arguably, not tied to either NHS or manufacturer organisations, they offer a unique view of the landscape from both perspectives. Almost one in 10, 9.5%, of those who responded to the survey fall into this category.

The issues noted within this collaboration theme, mainly fall into two broad categories:

- 1 – Lack of clarity and therefore disagreement around the applicability of the standards.
- 2 – Quality of documentation provided, with lack of engagement (from both sides) to address issues / concerns.

This can lead to CSOs having to navigate difficult conversations and can put strain on what should be a collaborative and transparent relationship between supplier and NHS organisation. Whilst some professional tension could be considered healthy within this relationship, active or passive disruption to this key process of DCRM can only have a negative impact.

However, it is worth noting that this challenge can also go the other way. There are instances where organisations exert excessive control, disregarding supplier expertise and dismissing valuable recommendations. This can result in poorly informed decisions, underutilisation of system capabilities, and an increased risk to patient safety.

This can be a difficult landscape to navigate. Industry CSOs face many challenges when conducting DCB0129 activities, as this comment from the 'Insights Survey' indicates: “[I have] recently retired from CSO consultancy for industry/suppliers (retired due to feeling current process is unsafe).”

Theme 7: Non-compliance by suppliers



A commonly reported situation is where a supplier is not compliant with DCB0129 requirements. When suppliers fail to adhere to DCB0129, it impacts the entire subsequent process of digital clinical safety. Non-compliance can complicate the CSO's ability to maintain comprehensive clinical safety documentation, as essential information from the supplier may be incomplete or absent. This makes it challenging to build a robust safety case and ensure that all hazards are adequately identified and mitigated. Ultimately, managing a non-compliant supplier places a heavy burden on CSOs, increasing workload, delaying project timelines, and heightening the risk of potential safety incidents.

Suppliers themselves face challenges when trying to adhere to the DCB0129 standards. Recruiting, or outsourcing CSOs can be a challenge, due to the niche expertise required.

Actionable insights

The Digital Health Networks Clinical Safety Officer (CSO) Council recommend that:

- Every healthcare organisation should ensure sufficient and dedicated clinical safety officer capacity. Ideally, organisations should conduct a thorough demand and capacity assessment to ensure they have sufficient digital clinical safety expertise and resources to effectively manage the end-to-end requirements of digital clinical safety. A national framework/benchmark would support this.
- Organisations should provide adequate access to ongoing digital clinical safety education/development that is accessible to all.
- There should be digital clinical safety representation at a board level.
- Organisations should undertake audit for DCB compliance. For deploying organisations, this should include supplier compliance with DCB0129 as their own compliance with DCB0160.
- There should be a framework relating to competency for clinical safety officers and an accompanying national syllabus relating to DCB and clinical safety training. This competency framework would allow for accreditation of the CSO role.
- The DCB standards should be updated with active engagement from the CSO community and the CSO Council. The CSO Council understand that NHS England have begun this process at the time of publication.
- DCB compliance should be a regulated requirement.



- A national platform should be utilised to share safety concerns and be the point of contact to escalate and action safety incidents.

Conclusion

The implementation of DCB0129 and DCB0160 standards is vital to ensuring patient safety. However, this process is often hampered by significant organisational barriers that impede effective adoption and integration. These barriers include a lack of awareness around the requirements and benefits of the process, resistance to change, and the chronic issue of insufficient resources - all of which are exacerbated by the lack of funding and pressures to complete tasks rapidly, often at the expense of thorough and systematic processes.

With greater clarity around these barriers, explored in this paper, organisations can make concerted efforts to address challenges locally, and by collectively doing so will contribute to system wide changes relating to digital clinical safety.

It is clear from the engagement with the CSO survey that the CSO community has a deep understanding of the challenges facing digital clinical safety. CSOs willingness to support compliance with standards and drive forward this agenda should be supported and maximised.

References

Ref	Title	Description	Source
1	NHS long term plan		NHS Long Term Plan
2	Digital clinical safety strategy		NHS England » Digital clinical safety strategy
3	Part of Applicability of DCB 0129 and DCB 0160 Background		Background - NHS England Digital
	DCB 0129 Standard Specification		https://digital.nhs.uk/binaries/content/assets/website-



			assets/isce/dcb0129/0129242018impguid.pdf
	DCB 0160 Standard Specification		https://digital.nhs.uk/binaries/content/assets/website-assets/data-and-information/information-standards/standards-and-collections/dcb0160/0160252018impguid.pdf